Remarks-Pending Rejections:

35 U.S.C. 102(b) Rejections

The rejection of Claims 9, 13, 14, 15, and 17 as being anticipated by Gaster (US 2001/0019055, hereinafter Gaster) was maintained. The rejection alleged that Gaster teaches the claimed process as evidenced at paragraphs 0017-0018 and figures 5-6.

In response to Applicant's response to the non-Final Office Action mailed February 23, 2007, the Final Office Action states that Applicant's argument that Gaster does not teach telescopically joining the overlapping bodies is misplaced "because it is clear from fig 5 of Gaster that the overlapping bodies are telescoped, i,e., lid 57 is telescoped within body 56."

35 U.S.C. 103(a) Rejections

The rejection was maintained against Claims 10 to 12 and 16 as being unpatentable over Gaster for the reasons provided for the rejection based on 102(b). Regarding claims 10 to 12, it was further alleged that it is well-known in the molding art to clean a molded product after molding and a molding apparatus before the next molding cycle. Thus, it was alleged, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to clean the excess sealing fluid from the claimed locations in order to produce a high quality product and to ensure a proper molding operation. Regarding claim 16, it was alleged that sealing clamps having airing and suction ports are well-known in the molding art as effective means for positioning and releasing a preform. Thus, it was alleged, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include airing and suction ports in the apparatus of Gaster in order to enhance the positioning and releasing of the perform within the apparatus of Gaster.

In response to Applicant's challenge of Gaster as being non-analogous art, the Final Office Action stated:

> In regard to non-analogous art, applicant is reminded that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Gaster is reasonably pertinent to the problem that the instant invention addresses, i.e., sealing capsules in order to avoid leaking of any content to the outside or contamination thereof. The process and apparatus of Gaster ensures that the content

within the container/capsule is not leaked by properly sealing the telescoped bodies of the container/capsule.

The Final Office Action provided US 3847694, US 4235832, US 4261947, and US 4628850 as being pertinent to applicant's disclosure.

Arguments:

Applicant respectfully requests withdrawal of rejections raised in the non-Final Office Action but not maintained in the pending Final Office Action:

A previous 102(b) rejection to Claims 9 and 13 as being anticipated by Bodenmann et al (USPN 4196565), was not presented but does not appear to have been withdrawn.

A previous 102(b) rejection to Claims 9, 10, 13, and 14 as being anticipated by Lebrun et al (USPN 4940499) was not presented but does not appear to have been withdrawn.

A previous 103 rejection to Claims 11 to 12 and 15 to 17 as being unpatentable over Lebrun was not presented but does not appear to have been withdrawn.

Applicant respectfully traverses all maintained rejections.

102(b) Rejection

Applicant respectfully traverses the 102(b) rejection. Applicant maintains the position that Gaster fails to disclose every element of the pending invention when the terms are given their plain meaning and read in light of the whole specification.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1063 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) (claim to a system for setting a computer clock to an offset time to address the Year 2000 (Y2K) problem, applicable to records with year date data in "at least one of two-digit, three-digit, or four-digit" representations, was held anticipated by a system that offsets year dates in only two-digit formats). See also MPEP2131.02 "The identical invention must be shown in as complete detail as is contained in the claim." *Richland*

> *v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1931, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Note that, in some circumstances, it is permissible to use multiple references in a 35 U.S.C. 102 rejection. See MPEP § 2131.01. [MPEP 2131.]
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> During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:
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> > The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).
>
> [MPEP 2111]

"During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation in light of the specification.). This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification." MPEP 2111.01 (I), references omitted.

"The ordinary and customary meaning of a term may be evidenced by a variety of sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips v. AWH Corp.*, 415 F.3d at 1314, 75 USPQ2d at 1327. If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant's use of the terms. MPEP 2111.01 (III), references omitted.

When talking with the Examiner, it became apparent that Applicant needed to clearly establish to where the sealing fluid goes to seal the overlapping body parts to distinguish the pending invention from Gaster. Applicant will focus on the two clauses identified during the telephone interview in Applicant's specification: page 3, lines 4 and 9. Applicant provides the following passage to assist with the clarification:

> The present invention aims at providing an improved method and apparatus for sealing telescopically joined capsules with coaxial partly overlapping body parts, through subsequent application of a sealing fluid and an improvement of the fluid injection phase in order to reach the maximum volume available in the overlap of the body parts while the capsule remains free of residual liquid on its surface.
>
> With respect to this object the present invention provides a method and an apparatus for sealing telescopically joined capsules with coaxial partly overlapping body parts as defined in the appended claims. Sealing clamps are used to seal efficiently hard capsules. Filled or empty capsules are to be oriented before the sealing operation. The sealing clamps hold each capsule in a precise and reproducible upright position. A known quantity of sealing fluid is injected **in the overlap** of the body parts within a well-defined volume. The excess of sealing fluid is removed from the outside of the capsule shell. Moreover the excess of sealing fluid is removed from the sealing clamp to prevent build-up of sealing fluid. Finally the capsule is released properly.
>
> The use of spray clamps instead of bushings or any other apparatus enables to limit the zone where the sealing fluid is injected **to the overlap** of the body parts. The design of the sealing clamp limits the location of the sealing fluid to the interior volume of the clamp. The excess of sealing fluid remaining in the clamp is recovered through suction channels. [Page 2, line 21 spanning to page 3, line 12, emphasis added.]

The sentence about the sealing fluid being injected "to the overlap" (page 3, line 9) is relevant to where the sealing fluid is limited rather than saying where the sealing fluid goes. In the pending application, sealing fluid is injected "in the overlap" (Pending Application, page 3, line 4). Put another way, the injection of the sealing fluid is limited "to the overlap" (Pending Application, page 3, line 9). The two clauses identified by the Examiner mean the same thing but are presented differently. Due to the tightening effect applied by the sealing clamp to the capsule, the zone of distribution of the sealing fluid is more limited to the overlap. This allows a more precise application of the sealing fluid in the overlap, so a reduced volume of sealing fluid is required, and, therefore, the risks of remoistening the outer surface of the capsule by the sealing fluid are minimized.

When read as a whole, the pending invention uniformly describes the application of the sealing fluid in the overlap of the coaxial body parts having an overlapped section when telescopically joined. When these paragraphs are read as a whole, in light of the whole specification, including claims, Applicant's invention requires:

(1) sealing a hard shell capsule

(2) having coaxial body parts which overlap when telescopically joined, comprising:

a. using a sealing clamp to clamp and hold the capsule in a precise and upright position,

b. injecting a quantity of sealing fluid in the overlap of the joined body parts; and

c. releasing the capsule.

The invention also concerns an apparatus comprising a sealing clamp to clamp and hold the hard shell capsule that is to be sealed by the method described.

Gaster does not describe every element of Applicant's invention, and, therefore, cannot anticipate it. The Final Office Action references FIG 5-6. However, the process to make the product in FIG 5-6 is the same as to make the product of FIG 1-3 (Gaster, [0018]), so the whole specification will be referenced to distinguish Gaster from the pending invention.

> **FIGS. 5 and 6** depict a process and product similar to the container **15**, except that this product is in the form of a cylindrical drum **51** of the type commonly used in various industries. The drum has a circular cross-section, formed of a body **56** and a lid **57**. The body has a flange **59** extending completely around its upper open end, and a mating flange **58** extending completely around therearound [sic]. The lid has a cross-section equal to the cross-section of the body, and the flange of the lid sits against the flange of the body as shown. The mold members **52** and **53** are similar in design to the mold members **11** and **12** of the earlier described embodiment, and have openings **54** and **55** into which the over-molding material may be inserted. Seals **61** and **62** are inserted into the mold members as shown to provide extra sealing between the members. The over-molding plastic material **30** is introduced into the mold members in a manner and under the conditions described with respect to **FIG. 3**, and provides a molded segment **64** around the flanges to lock the lid and body together[.] similar to the locking described with respect to **FIG. 3**. Openings **62** and **63** are provided in a spaced peripheral arrangement in the flanges **58** and **59** so that the material may flow through the openings for extra locking, as with the **FIG. 3** arrangement. The drum may be of any configuration useful in various industries. As is the case in the previously described embodiment, this drum may be used to enclose an inner container which holds the waste material, or my [sic] be sent to a customer

> who will place the waste material, such as sewage effluent, directly in the body **56** of the container, and then secure the lid **57** to the body in the manner described. [Gaster, page 2, bottom first col spanning to second col, emphasis added.]

"[A] principal object of [Gaster] is to form an **over-molded** product comprising multiple components secured by a thermosetting plastic material." Gaster, [0004], emphasis added. "The liquid plastic material is **introduced into a mold** which is positioned **around the abutting and adjacent** [flanges] of the components . . . ." Gaster, [0003], emphasis added. Gaster uses a clamp of any suitable means to clamp mold members together. [0017]. The mold members have central openings. [0016]. The two components are held in place by the central openings of the mold members, so the inner surfaces of the flanges are abutting. Furthermore, the flanges are placed in offset portions of the mold. The over-molding material is injected into the mold to form an outer solid mass of material which envelopes the abutting flanges of the components. [0017]. The material is now in the form of an outer solid mass of material 39 having a generally U-shaped configuration which envelops the flanges 22 and 23." Gaster, [0017]. Like the over-mold material in FIG 4, the over-molded material for the product of FIG 5-6, e.g., segment 64, is around the flanges and through the openings of the flanges of lid 57 and body 56 and does not go between lid 57 and body 56. See FIG 6.

Applicant appreciates the fact that in Gaster, the flanges have openings through which the molding material flows, e.g., 37 and 38 (FIG 1, page 2, col. 1, lines 1 to 3 and about lines 23 to 25) and 62 and 63 (Gaster, page 2, [0018, second column, about lines 18 to 22]). However, the molding material flows "through" the openings. Gaster does not disclose anything to indicate that the plastic material flows between either the abutting flanges or the components, e.g., the lid and the body in FIG 5. In fact, Applicant finds no description in Gaster of the mold material being anywhere except around, and through openings in, the flanges. The different shape of the drum in FIG 5-6 of Gaster does not result in Gaster describing all elements on Applicant's invention. It is Applicant's position that improper hindsight has been used if it is alleged that the plastic over-molding material is said to flow between the lid and body of any components discussed in Gaster.

To be clear, Applicant's invention requires that the sealing fluid be injected so it seals the capsule in the overlap of the coaxial, telescopically joined body parts of the capsule.

Applicant now directs attention to the specific independent claims to identify this requirement.

Claim 9: The essential elements of claim 9 are

(1) sealing a hard shell capsule

(2) having coaxial body parts which overlap when telescopically joined, comprising:

a. using a sealing clamp to clamp and hold the capsule in a precise and upright position,

b. injecting a quantity of sealing fluid in the overlap of the joined body parts; and

c. releasing the capsule.

Gaster fails to disclose at least two elements:

(A) The sealing process and apparatus in Gaster describe securing an over-molded product. From Gaster as a whole, the "outer solid mass" does not flow between components but secures them together by flowing around, and through openings in, flanges that are part of the components. Nothing in Gaster indicates that the molding material flows between flanges or the lid and body of the product in Gaster. Because of at least the requirement that the sealing fluid in Applicant's invention seal the capsule in the overlap of the coaxial, telescopically joined body parts, Gaster cannot anticipate Applicant's claim 9.

(B) Gaster also fails to describe "coaxial body parts which overlap when telescopically joined" with regard to lid 57 and body 56. To assist with this discussion, a few definitions relevant for "telescopically" are provided:

"telescopically" as it relates to parts, is "having parts that telescope"

"to telescope" means

"to slide or pass one within another like the cylindrical sections of a hand telescope",

"to force a way into or enter another lengthwise as the result of collision", or

"to become telescoped"

WEBSTER'S New Collegiate Dictionary, 1977, page 1198. A copy can be provided if needed.

For Applicant's invention, "to slide or pass one within another like the cylindrical sections of a hand telescope" is most consistent with the term used throughout the specification and claims.

In Gaster, lid 57 and body 56 have flanges that abut. The lid and body meet only as far as the flanges allow before abutting. Furthermore, it appears that lid 57 is supported by body 56 from the 90-degree bend on which lid 57 sits. See, e.g., FIG 5. Therefore, when Gaster is read as a whole, the lid and body cannot be telescoped like sections of a hand telescope. The text of Gaster may have the word "cylindrical" but it is modifying "drum" where drum is only part of the components. The two components cannot slide or pass one within another like the cylindrical sections of a hand telescope because the components are not cylindrical and have no corresponding surfaces able to slide one on the other when the components are mutually engaged or disengaged. Furthermore, the components have flanges that do not appear to be considered in the Final Office Action. These abutting flanges also distinguish the disclosure in Gaster from Applicant's invention.

For at least the forgoing reasons, all of the elements of Claim 9 of the pending invention cannot be described in Gaster. Applicant, therefore, respectfully requests the withdrawal of the 102(b) rejection of Claim 9. If the rejection is not withdrawn, to the extent that the Examiner relies on his personal knowledge for the basis of the 102(b) rejection, Applicants request an affidavit. 37 C.F.R. 1.104(d)(2).

Claim 13 and claims dependent thereon:

The non-Final and Final Office Action state: "Gaster teaches the claimed process as evidenced at paragraphs 0017-0018 and figs 5-6." Claims 13, 14, 15, and 17 do not concern a process but an apparatus. The non-Final Office Action is silent as to how Gaster anticipates the apparatus. The Final Office Action mentions that the amendment reciting that the capsule is made of pharmaceutical material is not germane to the patentability of the machine/apparatus; however, does not identify any part of Gaster as it relates to anticipating Applicant's apparatus.

Applicant incorporates herein the arguments previously made regarding how the product in Gaster is made with the over-molded section being on the outside of the product around, and through openings in, the flanges. Because Gaster concerns an outer molding and

Applicant's invention concerns an apparatus for, *inter alia*, providing a means to inject sealing fluid in the overlap of coaxial, telescopically joined body parts, Gaster does not anticipate the apparatus of Claims 13, 14, 15, and 17. Downsizing the mold and suitable clamp of Gaster will not describe Applicant's invention for at least an apparatus having a means to inject sealing fluid in the overlap of coaxial, telescopically joined body parts.

For at least the forgoing reasons, all of the elements of Claim 13, 14, 15, and 17 of the pending invention cannot be described in Gaster. Applicant, therefore, respectfully requests the withdrawal of the 102(b) rejection against these claims.

If the rejections are not withdrawn, to the extent that the Examiner relies on his personal knowledge for the basis of the 102(b) rejection, Applicants request an affidavit. 37 C.F.R. 1.104(d)(2). Applicant further requests more details regarding how Gaster anticipates Applicant's apparatus.

103(a) Rejection

Applicant respectfully traverses the 103(a) Rejection. Applicant believes that the procedural and substantive requirements to support the 103 rejection have not been and cannot be satisfied. Applicant also maintains the position that Gaster is non-analogous art and that it fails to describe Applicant's invention when the terms are given their plain meaning and read in light of the whole specification.

Before the mailing of the Final Office Action, the USPTO provided guidelines regarding obviousness rejections following the decision of *KSR Int'l Co. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 1997). Federal Register, Vol. 72, No. 195, 10/10/2007, page 57526. The notice states, in pertinent part:

> Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.
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> . . . .
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> . . . . The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. [*Id.*, 57528-57529.]

> Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court [in *Graham v. John Deere Co.*,383 U.S. 1, 148 USPQ 459 (1966)] are as follows:
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> (1) Determining the scope and content of the prior art;
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> (2) Ascertaining the differences between the claimed invention and the prior art; and
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> (3) Resolving the level of ordinary skill in the pertinent art.
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> Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. . . .
>
> The question of obviousness must be resolved on the basis of these factual determinations. While each case is different and must be decided on its own facts, the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. . . . .
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> . . . .
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> Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquiries. It must be remembered that while the ultimate determination of obviousness is a legal conclusion, the underlying *Graham* inquiries are factual. When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. . . . . Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.
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> Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103. 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability.
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> In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. What follows is a discussion of the *Graham* factual inquiries. [*Id.* at 57527, citations omitted.]

These passages can only be taken to mean that a *Graham* factual analysis is a necessary first step of every rejection based on obviousness and that the factual analysis must be articulated on the record.

In the non-Final Office Action and Final Office Action, with regard to Gaster, it is simply stated:

> Claims 10-12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaster (US 2001/0019055). The above teachings of Gaster are incorporated hereinafter. In regard to claims 10-12, it is well-known in the molding to clean a molded product after molding and a molding apparatus before the next molding cycle. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to clean the excess sealing fluid from the claimed locations in order to produce a high quality product and to ensure a proper molding operation. In regard to claim 16, sealing clamps having airing and suction ports are well-known in the molding art as effective means for positioning and releasing a preform. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include airing and suction ports in the apparatus of Gaster in order to enhance the positioning and releasing of the preform within the apparatus of Gaster.

First, Applicant challenges the sufficiency of the Final Office Action for failing to comply with the recent guidelines implementing the details required in obviousness rejections as presented in *KSR*. See, Federal Register, Vol. 72, No. 195, 10/10/2007, page 57526. Applicant contends that the reasons supporting the rejection are conclusory and do not provide the analysis required under *KSR*, citing *Graham*. See also, 35 U.S.C. 132. For example, it is stated that it is well known to clean a molded product after molding and a molding apparatus before the next molding cycle. Non-Final and Final Office Actions. Although the Final Office Action lists US patents for the state of the art, the Final Office Action fails to provide any details regarding for which claim(s) the references are being used as the state of the art and what each reference establishes as the state of the art.

Applicant requests a thorough *Graham* factor analysis of each reference relied upon for the obviousness rejection if the claims are not allowed. It is Applicant's position that the pending allegations lack sufficient details to shift the burden to Applicant because said allegations are insufficient to establish a prima facie case of obviousness and fail to comply with the decision in *KSR* and the guidelines published October 10, 2007 by the USPTO following *KSR*.

Second, Applicant again challenges the use of Gaster as non-analogous art and now challenges the use of the state-of-the-art references cited in the Final Office Action as non-analogous art. The MPEP states at 2141.01(a), Section I:

> The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the

particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

When responding to Applicant's challenge of Gaster as analogous art, the Final Office Action states, in pertinent part:

> In this case, Gaster is reasonably pertinent to the problem that the instant invention addresses, i.e., sealing capsules in order to avoid leaking of any content to the outside or contamination thereof. The process and apparatus of Gaster ensures that the content within the container/capsule is not leaked by properly sealing the telescoped bodies of the container/capsule.

Applicant disagrees with the statement regarding the problem to be solved.

> A prerequisite to making this [obviousness] finding is determining what is "prior art," in order to consider whether "the differences between the subject matter sought to be patented and the prior art are such that **the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art**." 35 U.S.C Section 103. Although Section 103 does not, by its terms, define the "art to which [the] subject matter [sought to be patented] pertains," this determination is frequently couched in terms of whether the art is analogous or not, i.e. , whether the art is "too remote to be treated as prior art." In re Sovish, 769 F.2d 738, 741, 226 USPQ 771, 773 (Fed.Cir. 1985). [*In re Clay*, 966 F.2d 656; 23 USPQ2d 1058, 1060 (Fed. Cir. 1992), emphasis added.]

In *Clay*, the invention was a process for storing refined liquid hydrocarbon product in a storage tank having a dead volume between the tank bottom and its outlet port. Two prior art references were cited. The court in *Clay* discussed the two factors both Applicant and Examiner have cited for evaluation of whether the references were proper. The court determined that the references were not within the same field and that the references were not proper because the problems to be solved were not reasonably pertinent to the problem of Clay's invention:

> Even though the art disclosed in [the] Sydansk [reference] is not within Clay's field of endeavor, the reference may still properly be combined with Hetherington if it is reasonably pertinent to the problem Clay attempts to solve. *In re Wood*, 599 F.2d at 1036, 202 USPQ at 174. A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the

> reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it. [Id. at 1060-1061, emphasis added.]

See also, Fed. Reg., Vol. 27, No 195, p 57528, citing MPEP 2141.02.

Like in *Clay*, the problem solved by the pending invention is different from the problem solved by the reference (Gaster).

Applicant incorporates herein all arguments provided *supra* when responding to the 102(b) rejection based on Gaster. Applicant further contends that the problem to be solved has been too simplified, improperly using hindsight, to derive Applicant's invention from Gaster. Applicant, therefore, provides an alternative interpretation of the problems solved in Gaster and the pending invention: In Gaster, the problem is to avoid high temperatures (e.g., between 400 and 600 degrees F) and forcing the melt into the mold cavity at pressures that are normally between 12,000 and 16,000 PSI. See Gaster, page 1, [0003].

However, the pending invention concerns sealing hard shell, coaxial, telescopically-joined body parts made of pharmaceutically acceptable material by injecting sealing fluid in the overlap of the joined body parts. Therefore, one of ordinary skill in the art of pharmaceutical development would not look to technology for making over-molded products using liquid plastic to avoid high heat and pressures to solve the problem solved by Applicant's invention.

In further support of Applicant's invention, Applicant directs special attention to uses of polydicyclopentadiene (PDCPD), the preferred molding material of Gaster, [0018]. A google search of polydicyclopentadiene provided many hits. The following is taken from the Wikpedia reference, the pdf is attached hereto as Appendix A:

> **Applications**
> Since PDCPD is still a young material, the number of applications is quite limited. The major success story is in the field of body panels, mainly for tractors, construction equipment, trucks and buses. In the industrial applications, the main success story is components for chlor-alkali production (e.g. cell covers for electrolyzers). **Other applications can be developed where impact resistance in combination with rigidity, 3D design and/or corrosion resistance is required**. [Emphasis added.]

Inappropriate hindsight has been used to mold the problem and to make Gaster appear relevant. The problems to be solved in Gaster are completely different than the problems

facing the inventors of the pending invention. Therefore, Gaster should not be found to be analogous art.

Last, assuming, *arguendo*, that Gaster is found to be analogous art, and this is not an acceptance of Gaster as a proper reference, Applicant contends that obviousness has not and cannot be established when the pending invention is appreciated in light of the specification and claims.

Applicant incorporates herein the arguments previously made herein regarding how the process and product in Gaster concerns an over-molded material being on the outside of the product around, and through openings in, the flanges and not between any component. Because of the discussion *supra*, it is Applicant's position that Gaster does not make Applicant's invention obvious where Applicant's invention concerns a method and an apparatus for sealing a hard shell capsule having coaxial body parts which overlap when telescopically joined where sealing fluid is injected in the overlap. The method was previous described and is incorporated herein. The apparatus comprises:

(1) a sealing clamp to clamp and hold the capsule in an upright position; and

(2) means to inject a sealing fluid in the overlap of the body parts.

As discussed already, Gaster fails to at least describe injection of a sealing fluid in the overlap formed from coaxial, telescopically-joined body parts. Therefore, Gaster should not be found sufficient to make Applicant's invention obvious.

Moreover, the obvious rejection concerns claims 10-12 and 16. Applicant is unable to locate in Gaster where the limitations of claims 10 to 12 and 16 are discussed. The Final Office Action also provides other references: US 3847694, US 4235832, US 4261947, and US 4628850. The Final Office Action provides no guidance as to which claims these references provide the state of the art and does not provide any information as to which rejected claim is made obvious in light of any of these four state-of-the-art references. The Final Office Action fails to comply with *KSR* and the new guidelines for rejecting claims based on 103. If the claims are not allowed, Applicant respectfully requests a more thorough *Graham* factor analysis in the Advisory Action regarding Gaster alone and in any combination with the references regarding the state of the art.

Applicant also contends that the four state-of-the art references are non-analogous art for reasons similar to the challenge of Gaster as non-analogous art.

Applicant respectfully requests the withdrawal of the 103(a) rejection for claims 10 to 12 and 16. If the rejection is not withdrawn, Applicants request a thorough *Graham* factual analysis in the Advisory Action, including an affidavit from the Examiner to the extent that the Examiner relies on his personal knowledge for the basis of the 103 rejection. 37 C.F.R. 1.104(d)(2). And, as previously requested, if the rejection is not withdrawn, Applicant requests specific citations to the "well-known" technology referenced in the rejection to allow Applicant an opportunity to review any references, including a thorough *Graham* analysis of each. 37 CFR 1.104, specifically, but not limited to, 37 CFR 1.104(c)(2).

Conclusion

Applicant believes that the claims are in order for allowance, early notice of which is requested. If Examiner has any questions concerning this application, Examiner is invited to contact the below-signed attorney. No fee is due. However, if a fee is found to be due, please charge any payment or credit any overpayment to Charge Account 16-1445.

Respectfully submitted,

/Mary J. Hosley/ Date: 31 December 2007

Mary J. Hosley, Attorney, Registration No. 48,324
Attorney for Applicant

Pfizer, Inc
150 East 42nd Street, Floor 5
New York, NY 10017-5612
Telephone No. 212.733-0460
Telefax No. 212.573-1939

Serial Application No. 10/795898

Case No. PC 25692a

APPENDIX A

Polydicyclopentadiene

Polydicyclopentadiene

From Wikipedia, the free encyclopedia

Polydicyclopentadiene (PDCPD) is a relatively new polymer which is formed through Ring opening metathesis polymerisation (ROMP) of Dicyclopentadiene (DCPD). PDCPD is the chemical name of the polymer and proves quite a challenge for non-chemists to pronounce. Since PDCPD is not a widely known and used material, the number of suppliers is small and tradenames make life easier for the users. The difference between the various systems lies in the type of catalyst used to create the polymer, but the final polymer properties are similar. Any difference which can be seen is often insignificant to the end user unless the application requires to go to the limits of the PDCPD material properties. The three tradenames are Telene, Metton and Pentam (see links to the respective companies below).

Contents

The Chemical System

The reacting system is formulated in such a way that two components need to be mixed at equal volume (1:1 ratio). Both components contain mainly DCPD with some additional additives. The difference between both components is crucial, but constitutes only a small fraction of the total formulation: the catalyst system is divided into two parts, each part going into a separate component. When both components are mixed, the complete catalyst system is recombined and becomes active. This is an important difference from other Reaction Injection Moulding (RIM) systems like polyurethane, since the reaction is not stoichiometric. The 1:1 ratio for DCPD moulding is not critical since this is not a combination of two different chemical elements to form a specific matrix. Significant changes in ratio will slow down the system's reactivity because fewer active reaction nuclei are being formed. This also changes the final properties somewhat. The current industrial pumps used on RIM equipment are more than accurate enough to ensure that the mixing ratio stays within the necessary limits.

Equipment

DCPD resins are transformed using high pressure RIM equipment as used in the polyurethane industry, with some small changes to be considered. As a reference, a widely used machine to inject DCPD resins is the Cannon A-100 fitted with a DCPD kit. The most important change is that the resin can never be in contact with air or moisture, which required a nitrogen blanket in the tanks. The tools or moulds are closed tools and are being clamped using a hydraulic press. Due to the fact that the resins shrink about 6% in volume during reaction, these presses (also called clamping units) don't have to handle high

pressures such as for Sheet Moulding Compound (SMC) or expanding polyurethane.

Tooling

Most tooling for PDCPD is made from aluminium. Flat parts can be made from machined aluminium while deeper 3D-shaped parts are often made in cast aluminium tools. It is important to know that these tools have to take the volumetric shrinkage into account, cannot have any undercuts and need gaskets all around the cavities.

Process Considerations

The liquid resin has a density of 0.97 and reacts into a solid with a density of 1.03 which constitutes a volumetric shrinkage of 6%. Since most parts are panels, most of the shrinkage will happen in the Z-axis (thickness). This makes the parts self-demoulding as they do no have a good contact with the core side of the tool [The core side is the side which will be the back side of the part. The front side of the part is called the matrix side].

A reacting system is always governed by temperature - in any form. This means that the temperature of the liquid components has a strong influence on the reactivity. So do the temperatures inside the tool. To ensure that one side has an excellent surface finish, the temperature on that side needs to be higher than on the core side. Both tool-halves are therefore tempered at a different temperature with typical values of 60°C and 80°C.

Typical cycle times for moulding parts range between 3 and 5 minutes.

Properties

PDCPD has a unique combination of properties with the most important being:

- high impact resistance
- high chemical corrosion resistance
- high Heat deflection temperature (HDT)

For the best information on all properties of this resin system and polymer, it is best to contact the material supplier or to visit their respective websites.

PDCPD does not contain any fiber reinforcement although a fiber reinforced version has been developed by Telene S.A.S. PDCPD allows to vary the thickness throughout a part, to incorporate ribs and to overmould inserts for an easy assembly of the parts. PDCPD cannot be painted in mass and needs to be painted after moulding.

Applications

Since PDCPD is still a young material, the number of applications is quite limited. The major success story is in the field of body panels, mainly for tractors, construction equipment, trucks and buses. In the industrial applications, the main success story is components for chlor-alkali production (e.g. cell covers for electrolyzers). Other applications can be developed where impact resistance in combination with

rigidity, 3D design and/or corrosion resistance is required.

Economic considerations

PDCPD has proven to be economically interesting when considering large parts (>5 kg or >1m²) in low to medium series (1,000 to 20,000 parts per year). Factors that make this case are:

- low initial investment versus injection moulding or SMC
- high capacity due to the low cycle times compared to hand lay-up or Resin transfer moulding (RTM)
- fast development cycles for new projects

External links

- Telene S.A.S. : Telene resin system (http://www.telene.com/)
- Metton America Inc : Metton resin system (http://www.metton.com/)
- Rimtec : Pentam resin system (http://www.rimtec.co.jp/)

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Category: Polymers